

CLAIMS

1. An oral sustained release pharmaceutical composition comprising a plurality of granules having diameters of not more than 1000 μm , each of which 5 comprises a nucleus granule containing beraprost sodium, and a coating agent constituting at least two skin layers including (1) a skin layer containing a relatively water-insoluble macromolecular substance and (2) a skin layer containing a hot-melt low-melting substance, said nucleus granule being coated with said coating agent.
- 10 2. The oral sustained release pharmaceutical composition according to claim 1, wherein said relatively water-insoluble macromolecular substance is at least one selected from the group consisting of water-insoluble alkyl cellulose ether derivatives, water-insoluble acrylic polymer derivatives and water-insoluble 15 vinyl derivatives.
3. The oral sustained release pharmaceutical composition according to claim 1 or 2, wherein said hot-melt low-melting substance has a softening point of not higher than 70°C.
- 20 4. The oral sustained release pharmaceutical composition according to any one of claims 1 to 3, wherein said hot-melt low-melting substance is at least one selected from the group consisting of higher alcohols, higher fatty acids, higher fatty acid glycerin esters, waxes and saturated hydrocarbons.
- 25 5. The oral sustained release pharmaceutical composition according to any one of claims 1 to 4, wherein the weight ratio of (1) said skin layer containing the relatively water-insoluble macromolecular substance to (2) said skin layer containing the hot-melt low-melting substance is within a range between 1:9 and

9:1, preferably between 3:7 to 7:3.

6. A process for producing an oral sustained release pharmaceutical composition comprising a plurality of granules having diameters of not more than 1000 μm , each of which comprises a nucleus granule containing beraprost sodium, and a coating agent constituting at least two skin layers including (1) a skin layer containing a relatively water-insoluble macromolecular substance and (2) a skin layer containing a hot-melt low-melting substance, said nucleus granule being coated with said coating agent.